

L'ORÉAL

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S C I E N C E S D U V I V A N T

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Comments on the draft « ICCVAM Minimum Performance Standards : In Vitro Human Skin Model Systems for Skin Corrosion »

The definition of minimum criteria of biological systems and performances on their uses is an essential guarantee to obtain relevant in vitro data and recognition of the method by regulatory authorities.

The initiative of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Dermal Corrosivity and Irritation Working Group (DCIWG) corresponds to a real need for academics and industrial companies.

We have some suggestions in order to implement the draft.

The EPISKIN™ model has been validated through the ECVAM validation process and is on the market today. We suggest **to mention that EPISKIN™, besides EpiDerm™, has a commercially available models for skin corrosivity assessment, page 4 line 20 and p7 line 17.** In the same way we suggest to suppress the part of sentence “ **and recommended as an alternative to EPISKIN™ page 3 line 17.**

The ECVAM validation process demonstrated the ability of the EPISKIN™ test to discriminate corrosives from non-corrosives but also its ability to identify correctly known R35/I and R34II&III chemicals. This important advantage as regard to the UN packing groups classification should be mentioned in the draft. The addition of a sentence such as **‘including the discrimination between R35 (UN packing group I) and R34 (UN packing groups II&III)** after the citations (2,12,16) *page 3 line 14* would complete the information provided on Table 1 concerning the corrosive subclasses recognized by some authorities.

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Some typing errors have been found in the draft:

- *page 3 line 18*: the **citation 2** should be suppressed, since the ECVAM publication do not mention EpiDerm.
- *page 4 line 21*: citation number **22** instead of 221
- *page 5 line 19*: the exposure period of **4 hours** should be omitted since the draft described the method and predictive model for only two classes (corrosives/non-corrosives)(see prediction model *page 7*)
- *page 6 line 9*: add '**or**' between glacial acetic acid and 8N KOH
- *page 6 line 22*, the word '**Cell**' should be suppressed
- *page 12*: the title of the Table 3 should be corrected as " Accuracy of the Validated Human Skin Model **EPISKIN™** Test Method for Skin Corrosion assessment"

We insist on the relevance of the draft proposed by the ICCVAM Dermal Corrosivity and Irritation Working Group and thank you for the opportunity to comment.

We hope the proposed modifications would help users of the method to better evaluate chemicals.

Sincerely,

Roland Roguet

/s/